AMENDMENT

Claim 1 has been amended to correct an obvious syntax error in the previous claim amendment, in stating "denaturation or degradation."

REMARKS

The Examiner requires Applicant to provide information under 37 CFR 1.105. It is respectfully submitted that the following remarks are responsive to this requirement.

The Examiner has identified five separate questions to assist in understanding the nature of the solvent and the polymer. It appears that these questions arise from the use of the term "dissolved polymer." The meaning of this term is explained in response to the first question, with further discussion and clarification provided in response to the balance of the questions.

1) If the polymer has been dissolved, how can it then be solidified?

It is respectfully submitted that in the context of the present invention, the term "dissolved" is understood to mean that the polymer is solvated by the solution, and not broken down to individual atoms or monomers. In other words, the chemical structure of the polymer is not changed when it is dissolved. The term "dissolution" is defined as "molecular dispersion of a solid in a liquid." Hawley's Condensed Chemical Dictionary, Twelfth Edition (copy attached). Thus, a dissolved polymer (which is a large molecule) is dispersed in a liquid. There are many texts that discuss dissolving polymers in solvents, such as Allcock et. Al. Contemporary Polymer Chemistry, Second Edition, 1990, at page 409 (copy attached). The solubility parameter of a polymer can be experimentally determined or calculated. "The solubility parameters are particularly useful when studying how capable is a polymer to being dissolved in a given solvent." See the webpage "Thermodynamic Considerations for Polymer Solubility at http://pslc.ws/macrog/property/solpol/ps4.htm, which is published by the Polymer Science Learning Center at the University of Southern Mississippi.

The term "dissolved polymer" additionally is common in the art, and a word search of this exact phrase in the US Patent databases results in identification of literally hundreds of patents using this term. See, e.g., US Patent No. 6,262,159; 4778,836; 4,099,218; 4,212,312. Indeed, the prior art documents cited by the Examiner (e.g. US 5,868,103 to Yeh et al.) describe methods in the context of which polymers are dissolved and later on solidified again. Standard emulsion methods for the encapsulation as disclosed in EP 442 671, mentioned in the background section of the present application, use such solutions and solidify the polymer simply by removing the solvent.

It is respectfully submitted that the patent application is written for the person skilled in the art. In the understanding of the prior art, a dissolved polymer is a polymer that is solvated, or caused to go into solution. Thus, a dissolved polymer is a molecular dispersion of a solid in a liquid. The dissolved polymer is, in the context of the present invention, capable of being precipitated or caused to come out of solution. The polymer is not, as seems to be implied in the "Request for Information" disintegrated to monomers or carbon atoms.

2) How can it be said in step b) that only the polymer is solidified?

The relationship of the components in the composition can be understood as follows:

In step a) according to the invention, a suspension of the active substance is produced. A suspension, by definition, is a particulate solid in a liquid. Thus, in step b), the active agent is already present in solid form and does not change its state any more. As a matter of fact, it is one of the advantages of the invention that in step a) fine particles of the active agent are produced in situ, and in step b) these fine particles can be directly encapsulated/embedded in a polymer matrix. Thus, the method according to the invention is very convenient and avoids shear forces which are otherwise needed to de-agglomerate solids of active agents added in a conventional manner as a powder to the system.

In summary of the method of the present invention, it is submitted that this method starts with two solutions: a first solution of an active agent, and a second solution of a

polymer. Once the solution of the active agent is added to the solution of the polymer in step a), the active agent precipitates (hence the name in-situ-precipitation) and is as solid as it needs to be in the final microparticle formulation. All that is required to accomplish this is that the solvent that dissolves the polymer does not dissolve the active agent. In this case, the solvent of the active agent will diffuse into the solvent of the polymer, and the active agent will find itself in a solvent system after being added to the polymer solution where its dissolution coefficient is exceeded. The solvent which had been used to dissolve the active agent now serves as co-solvent for the polymer. Since the active agent is not soluble in the polymer solvent as well as in the formed mixture of polymer solvents, the active agent is forced to precipitate in-situ. This may require some testing of solvent combinations, but such tests can be carried out in straightforward and routine way with a number of test-tubes and a pipette. Although the method is simple to put into practice, it becomes apparent from the prior art that no one had the idea of manipulating the composition based on solubility in the manner as claimed, and therefore would have had no reason to choose suitable solvents in accordance with the teaching provided in the application.

In step b), the only substance that remains dissolved in the solvent at the beginning of this step is the polymer. The active agent is already solid. Various methods for the solidification of the polymer can be applied, e.g. a method wherein the polymer solution containing the suspended particles of the active agent is emulsified in an aqueous solution, and the solvent for the polymer is removed, or a method wherein an aqueous surfactant solution is added to the system containing the dissolved polymer and the suspended active agent (e.g. page 4, lines 9 to 27 of the present application), and the polymer solvent is allowed to diffuse into the aqueous phase, leaving behind particles of the solid polymer and the (previously solidified) active agent.

In view of the above comments, it is believed that the remaining questions can answered together:

3) Which surfactant solution is able to reconnect the polymer and solidify it as opposed to all that remains in the suspension?

4) Aren't all elements in the suspension of step (a) solidified?

5) How can a polymer that has been broken up be the only part of the suspension that is solidified?

As explained above, the term "dissolved polymer" is understood to mean that the polymer is solvated by the solution, and not broken down to individual atoms or monomers. There is therefore no need to "reconnect" the polymer since the polymer will stay intact on a molecular level. The removal or replacement of the solvent is sufficient in order to solidify the polymer. Once the polymer is solidified (i.e. after step (b)), all essential components discussed in the method claim are solid and the previously solidified particles are encapsulated in the polymer.

The Request provides further comment asserting that the claim is "amorphously claimed such that a reasonable search of the art... is difficult at best." Applicants appreciate the challenges in searching this technology using the existing Patent Office Classification System and databases. This, however, is always the case in the search of prior art, particularly in method-based inventions. Applicants are entitled to claim their invention as they see fit, and claim formats based on functional definitions are sanctioned approaches for claiming. "There is nothing inherently wrong with defining some part of an invention in functional terms." MPEP 2173.05(g)

It is manifestly improper to limit the scope of a patent claim to specific examples provided in the specification on the basis that it is difficult to search the invention. Such a limitation clearly allows competitors to freely utilize the core principles of the invention as

taught by the present specification, while technically avoiding the scope of the claim. Such arbitrary limitations to the protection of inventions run afoul of the founding principles of the patent system, which promote disclosure of inventions by affording inventors limited terms of exclusive rights to their inventions. If limitation of claims to the examples in order to facilitate internal Patent Office searches were the consistent policy of the Patent Office, inventors will be driven to maintain advantageous and unique methods such as described in the present application as trade secret, with the undesired result that future developers would not have benefit of the present knowledge.

The use of functional language for claiming is particularly required to afford proper scope of protection in the present application. As has been discussed, the specific identify and combination of solvents selected for any given process depends on the identity of the given active substance and/or a certain polymer. Therefore, the functional definition of L1 and L2 as it appears in the present claim is fully appropriate, since the exact chemical nature of the suitable solvents will depend on which active agent needs to be encapsulated, and which polymer is selected for this purpose. The method as introduced to the world in the form of the present application is extremely versatile in this respect, and can be applied to a broad variety of agents/polymers, and a solvent which works very well for one active agent may not be useful for another one. Therefore, a limitation of the claims to certain classes/types of solvents would unduly limit the scope of the invention.

Additionally, it should particularly be noted that breadth does not render a claim to be unclear or indefinite. As indicated under item 2 above, only simple routine tests are required in order to establish whether a solvent is able to dissolve a given substance or not. In addition, monographs and databases both in the pharmaceutical and the non-pharmaceutical field provide ample information on the solubility of substances. Thus, the skilled person intending to follow the teaching of the present application will not be faced with an undue burden. It is noteworthy that even the EPO, which is usually particularly critical with respect to functional definitions, accepted the language of the present claims.

CONCLUSION

In view of the above amendments and remarks, it is respectfully submitted that the foregoing is fully responsive to the outstanding Request for Information. Favorable examination and passage of the above application to issue is earnestly solicited. In the event that a phone conference between the Examiner and the Applicant's undersigned attorney would help resolve any issues in the application, the Examiner is invited to contact said attorney at (651) 275-9811.

Respectfully Submitted,

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